



## **Comments to the Clinical Laboratory Improvement Advisory Committee (CLIA)**

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIA) on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) personnel requirements. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Since the inception of CLIA, the quality of laboratory testing has improved even with the rapid changes in technology and integration of the healthcare delivery system. Clinical laboratories are no longer just stand-alone sites but are an integral part of the health systems, which includes at least one hospital and at least one group of physicians providing comprehensive care (including primary and specialty care) who relate to each other and with the hospital through common ownership or joint management. Moreover, these healthcare systems are using advances in technology to perform clinical laboratory testing in a myriad of settings that are closer to the patients. The CAP believes that CLIA provides an adequate baseline to ensure the accuracy and reliability of clinical laboratory results but recognizes that specific updates to CLIA are needed to address the changes in practice and technology to accommodate today's practice.

The CAP supports CMS's effort to modernize CLIA personnel requirements and proposes the following recommendations.

- The CAP believes personnel requirements should be commiserate with the clinical laboratory related activities. Nurses perform laboratory-related functions such as point-of-care testing (POCT), specimen collection, and test ordering, which are not their primary job functions, but rather secondary tasks performed outside of the central laboratory. Specifically, the CAP recommends CMS create nursing as a separate qualifying degree with criteria:
  - Leveraging POCT in settings of a hospital or health care facility where specialized or intensive treatment (eg, ICU) is provided.
  - Allowing trained and experienced nurses to fulfill the role of technical consultant and general supervisor under the supervision of pathologists.
  - Expanding this designated nurse qualified category to include other allied health professionals (eg, respiratory therapists, interventional radiology technologists, and cardiac catheter technologists with bachelor's degrees).
- The CAP recommends CMS allow general supervisors to perform competency assessments of moderate- and high-complexity personnel.



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- The CAP recommends CMS maintain the current level of experience and training required to determine potential personnel eligibility. In addition, the CAP believes CMS should provide the laboratory director with additional flexibility in order to identify and train potential personnel who meet the minimum educational coursework requirements.
- The CAP recommends CMS allow for a centralized competency assessment to be performed if the assessment addresses any variations in the testing in the different testing locations.
- The CAP recommends CMS consider the physical and non-traditional degrees that include human biology course work with robust personnel experience and training requirements to ensure these individuals have enough knowledge base to perform clinical laboratory testing.